

Amendments to the claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A method of enhancing an immune response to an antigen in a mammal, comprising administering to the mammal a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof, and 2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant.

2. (Currently amended) A method according to claim 2, wherein the antigen or immunogenic derivative thereof is derived from an organism selected from the following group: of: Human Immunodeficiency virus HIV-1, human herpes simplex viruses, cytomegalovirus, Rotavirus, Epstein Barr virus, Varicella Zoster Virus, from a hepatitis virus such as hepatitis B virus, hepatitis A virus, hepatitis C virus and hepatitis E virus, from Respiratory Syncytial virus, parainfluenza virus, measles virus, mumps virus, human papilloma viruses, flaviviruses or Influenza virus, from Neisseria spp, Moraxella spp, Bordetella spp; Mycobacterium spp., including M. tuberculosis; Escherichia spp, including enterotoxic E. coli; Salmonella spp.; Listeria spp; Helicobacter spp; Staphylococcus spp., including S. aureus, S. epidermidis;; Borrelia spp; Chlamydia spp., including C. trachomatis, C. pneumoniae; Plasmodium spp., including P. falciparum; Toxoplasma spp., and Candida spp.

3. (Currently amended) A method of reducing the severity of a cancer in a patient, comprising administering to a patient in need thereof a safe and effective amount of 1) an IL-18 polypeptide or bioactive fragment or variant thereof and 2) an immunogenic composition comprising a tumour-associated antigen or immunogenic derivative thereof and a saponin adjuvant.

4. (Currently amended) A method according to claim 3, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group comprising: of: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or and her 2 neu.

5. (Currently amended) A The method according to any of claims 1 to 4, wherein the IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously, separately or sequentially in any order.

6. (Currently amended) A- The method according to claim 5 wherein ~~the the TH-1 cytokine~~ IL-18 polypeptide or bioactive fragment or variant thereof and the immunogenic composition are administered simultaneously in the form of a combined pharmaceutical preparation.

7. (Currently amended) A The method according to any of claims 1 to 6, wherein the IL-18 polypeptide or bioactive fragment or variant thereof is from human or murine origin.

8. (Currently amended) A- The method according to claim 7, wherein IL-18 is the polypeptide of SEQ ID NO.:6 or SEQ ID NO.:7 or bioactive fragment or derivative thereof.

9. (Currently amended) A The method according to any of claims 1 to 8, wherein the saponin adjuvant is chosen from the group of: QS-21 ~~or~~ and QS-17.

10. (Original) A combined preparation comprising as active ingredients the following individual components: (1) IL-18 polypeptide or bioactive fragment or variant thereof and (2) immunogenic composition comprising an antigen and a saponin adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, autoimmune diseases and related conditions.

11. (Currently amended) A The combined preparation according to claim 10, wherein components (1) and (2) are admixed in a composition.

12. (Currently amended) A The combined preparation according to claim 10, ~~or 11~~ wherein the immunogenic composition comprises a tumour-associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

13. (Currently amended) A The combined preparation according to claim 12, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group comprising of: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or and her 2 neu.

14. (Currently amended) A The combined preparation according to any of claims 10 ~~to~~ 13, wherein the IL-18 polypeptide or bioactive fragment or variant thereof is from human or murine origin.

15. (Currently amended) A The combined preparation according to claim 14, wherein IL-18 is the polypeptide of SEQ ID NO:6 or SEQ ID NO:7 or bioactive fragment or derivative thereof.

16. (Currently amended) A The combined preparation according to any of claims 10 ~~to~~ 15, wherein the saponin adjuvant is chosen from the group of: QS-21 or and QS-17.

17. (Currently amended) Combined The combined preparation as claimed in any of claims 10 ~~to~~ 16 ~~in which~~, wherein the immunogenic composition additionally comprises an immunostimulant chemical selected from the group comprising of: 3D-MPL, cholesterol, CpG oligonucleotide containing at least one immunostimulatory CG dinucleotide, aluminium hydroxide, aluminium phosphate, and tocopherol, and an oil in water emulsion or a combination of two or more of the said adjuvants.

18. (Currently amended) Combined The combined preparation as claimed in claim 17, wherein the immunogenic composition adjuvant comprises 3D-MPL, QS21, cholesterol, an oil in water emulsion.

19. (Currently amended) Combined The combined preparation as claimed in claim 18, wherein the oil in water emulsion comprises squalene, tocopherol, and polyoxyethylenesorbitan monooleate (Tween 80).

20. (Currently amended) Combined The combined preparation as claimed in claim 17, wherein the immunogenic composition comprises QS21, cholesterol, and a CpG oligonucleotide containing at least one immunostimulatory CG dinucleotide.

21. (Currently amended) Combined The combined preparation as claimed in ~~any of claims 10 to 20~~, wherein both active components are in the form of injectable solutions.

22. (Currently amended) A pharmaceutical kit comprising as active ingredients ~~the following individual components~~: (1) an IL-18 polypeptide or bioactive fragment thereof; and (2) an immunogenic composition comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, the active ingredients being for the simultaneous, separate or sequential use for the prophylaxis and/or treatment of infectious diseases, cancer, and auto-immune diseases.

23. (Currently amended) A The pharmaceutical kit according to claim 22, wherein the immunogenic composition comprises a tumour-associated antigen or immunogenic derivative thereof and is prophylactically or therapeutically active against cancer.

24. (Currently amended) A The pharmaceutical kit according to claim 23, wherein the tumour-associated antigen or immunogenic derivative thereof is selected from the group ~~comprising of~~: an antigen from the MAGE family, PRAME, BAGE, LAGE 1, LAGE 2, SAGE, HAGE, XAGE, PSA, PAP, PSCA, prostein, P501S, HASH2, Cripto, B726, NY-BR1.1, P510, MUC-1, Prostase, STEAP, tyrosinase, telomerase, survivin, CASB616, P53, or and her 2 neu.

25. (Currently amended) A The combined preparation as claimed in ~~any of~~ claims 10 to 20 for use in ~~medicine~~ medicine.

26. (Currently amended) A The method as claimed in ~~any of~~ claims 1 to 9, which comprises the use of a combined preparation according to ~~any of~~ claims 10 to 20.

27.-32. (Cancelled).

33. (New) A method for the prophylaxis and/or treatment of a patient suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions, and already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment or variant thereof.

34. (New) A method for the prophylaxis and/or treatment of a patient suffering from or susceptible to infectious diseases, cancer, autoimmune diseases and related conditions, and already primed with an immunogenic composition, comprising an antigen or immunogenic derivative thereof and a saponin adjuvant, comprising administering to the patient a safe and effective amount of an IL-18 polypeptide or bioactive fragment or variant thereof.

35. (New) The method according to claims 33, wherein the antigen is a tumour-associated antigen, and the cancer is selected from the group ~~comprising of~~: breast cancer, lung cancer, NSCLC, colon cancer, melanoma, ovarian cancer, bladder cancer, head and neck squamous carcinoma, ~~and~~ ~~oesophagus~~ esophageal cancer.

36. (New) The method according to claim 33, wherein the IL-18 polypeptide or bioactive fragment or variant thereof is from human or murine origin.

37. (New) The method according to claim 36, wherein IL-18 is the polypeptide of SEQ ID NO.6 or SEQ ID NO.7 or bioactive fragment or derivative thereof.

38. (New) The method according to any claim 33, wherein the saponin adjuvant is chosen from the group of: QS-21 and QS-17.